



FOOD, DRUGS, AND THE ENVIRONMENT: HOW THE FOOD AND DRUG ADMINISTRATION HAS INTERACTED WITH THE NATIONAL ENVIRONMENTAL POLICY ACT OF 1969

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FOOD, DRUGS, AND THE ENVIRONMENT: HOW THE FOOD AND
DRUG ADMINISTRATION HAS INTERACTED WITH THE
NATIONAL ENVIRONMENTAL POLICY ACT OF 1969.

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I. introduction

The National Environmental Policy Act of 1969 (NEPA) requires all federal agencies to consider the environmental impact of major regulatory decisions. The Food and Drug Administration (FDA) ensures that every element of food and drugs used by people or animals is safe for use or consumption. Though the FDA is obliged to follow NEPA's statutory mandates, it is not apparent that the scope of the FDA's jurisdiction embraces areas that pose any threat to the environment.

This paper examines the nature and extent of the FDA's interaction with NEPA throughout the statute's thirty year history. From initial confusion over how NEPA should actually affect the FDA's decision making to the current regulatory muddle over biotechnology, the FDA and NEPA have an extensive history. When Congress first passed the statute, the agency questioned whether it had the authority or obligation to base decisions on environmental concerns revealed through NEPA. That essential question pervades the FDA's interactions with NEPA, as each major encounter between the FDA and NEPA demonstrate that the FDA has never fully embraced the statute. While the FDA has complied with legal obligations mandated by NEPA, the agency operates from the baseline assumption that ensuring the safety of food and drugs has little to do with the environment.

On its face, this assumption appears reasonable and prudent. The FDA's fundamental responsibility is the extensive health and safety review of anything that may enter the American food or drug supply. To consider how the regulation of food and drugs could impact the environment could distract the FDA from

its primary mission. It is the goal of this paper to challenge these assumptions. This paper examines a series of cases in which the regulatory decisions made by the FDA did have a secondary impact, or potential effect on the environment. Though certainly the exception rather than the rule, FDA decision making can impact the environment. In addition to highlighting specific cases the FDA has confronted, the paper also analyzes the regulatory framework which the FDA has enacted to comply with NEPA, from its initial efforts in the early 1970's through the regulatory reform era of the late 1990's.

The paper proceeds in three parts. Part II provides an overview of NEPA. The section examines the statutory text and foundational case law to understand how the statute operates and the obligations it imposes on agencies. The section also examines the legislative history of the statute to determine to what extent, if any, Congress directly addressed the issue of how food safety or human health could impact the environment. Part III examines the FDA and the statutes it administers, the Food, Drug, and Cosmetic Act (FDCA). The purpose of the section is to outline the scope of the agency's jurisdiction and highlight those areas of jurisdiction where decision making could affect the environment.

In Part IV, the paper takes a largely historical approach to analyze how the FDA and NEPA have interacted. In six major episodes, or 'rounds,' the FDA has confronted its obligations under NEPA. There are two categories of episodes: those in which the FDA has taken steps, some more grudging than others, to comply with NEPA and those in which NEPA could have played a more extensive role in FDA decision making to identify or avoid environmental harm.

Several of these six rounds have been independently addressed by academic literature. This paper does not attempt to replicate the scope or detail of those efforts. The principal intent of this paper is to compile all these episodes in one place – to examine the FDA’s interaction with NEPA holistically and to observe change in attitudes and strategies through time.

II. THE POWER AND EXTENT OF NEPA

A. Introduction to the Statutory Text.

The National Environmental Policy Act of 1969 (NEPA) is one of the most important elements of federal legislation enacted to protect the environment.¹ The statute has the potential to reach into every agency of the federal government and alter that agency’s behavior. Importantly, NEPA contains a broad and powerful statement of Congressional policy to protect the environment and to hold the government environmentally accountable for its actions. NEPA was groundbreaking legislation for its time, passed before other well known environmental statutes such as the Clean Air Amendments of 1970² and the Endangered Species Act of 1973³ and today remains a powerful tool for environmental protection.

NEPA is divided into two sections. Title I contains the broad statement of national environmental policy and the “action-forcing” components of the statute.⁴

¹Pub. L. No. 91-190, 83 Stat. 852 (1970); codified at 42 U.S.C. §4321-4370 (1999).

²Pub. L. No. 91-604, 84 Stat. 1676 (1970); codified at 42 U.S.C. §7401-7671 (1999).

³Pub. L. No. 93-205, 87 Stat. 884, (1973); codified at 16 U.S.C. §1131-1544 (1999).

⁴See Pub. L. No. 91-190 §101-105 (1970); Because most literature discussing NEPA refers to the law in terms of the original statute, for consistency, the rest of the paper will refer to

Title II establishes the Council on Environmental Quality (CEQ) which is the regulatory body charged with overseeing NEPA implementation.⁵ Section 101 of NEPA contains a rather eloquent and extensive statement of national environmental policy that identifies many threats to the environment such as population growth, resource exploitation and “expanding technological advances.”⁶ The declaration further charges the federal government “to use all practicable means and measures . . . to create and maintain conditions under which man and nature can exist in productive harmony, and fulfill the social, economic, and other requirements of present and future generations of Americans.”⁷ The tone of this section continues to expound lofty goals by committing the government to “fulfill the responsibilities of each generation as trustee of the environment for succeeding generations . . . [to] attain the widest range of beneficial uses of the environment without degradation, risk to health or safety, or other undesirable and unintended consequences.”⁸ This part of the statute is commonly referred to as substantive NEPA. However, despite the impressive language of this national environmental policy, nothing in this section was drafted with any binding legal force.

Section 102 of NEPA is often referred to as the “action-forcing” part of the statute because it is the only part of NEPA that has any real bite in forcing the government to comply with the policy laid out in Section 101. The section begins by stating the directives that follow are to be complied with “to the fullest

NEPA’s original sections rather than the codified version (i.e. NEPA §xx).

⁵See NEPA §201-209 (as amended by Pub. L. 94-52 §3, 89 Stat. 258 (1975)).

⁶NEPA §101(a).

⁷*Id.*

⁸NEPA §101(b)(1), (3).

extent possible.”⁹ The statute then, rather broadly, states that the policies, regulations and laws of the country “shall be interpreted and administered in accordance with the policies set forth in this Act.”¹⁰ Section 102(2) of NEPA lists several duties that “all agencies of the federal government”¹¹ should take to effectuate these goals. These obligations include: “utiliz[ing] a systematic interdisciplinary approach which will insure the integrated use of the natural and social sciences and the environmental design arts in planning and in decisionmaking which may have an impact on the human environment;”¹² and “identify[ing] and develop[ing] methods and procedures.. which will insure that presently unquantified environmental amenities and values may be given appropriate consideration in decision-making along with economic and technical considerations.”¹³ Buried in this list, §102(2)(c) requires the federal government to:

include in every recommendation or report on proposals for legislation and other major Federal actions significantly affecting the quality of the human environment, a detailed statement by the responsible official on – (i) the environmental impact of the proposed action; (ii) any adverse environmental effects which cannot be avoided should the proposal be implemented, (iii) alternatives to the proposed action, (iv) the relationship between short-term uses of man’s environment and the maintenance and enhancement of long-term productivity, and (v) any irreversible and irretrievable commitments of resources which would be involved in the proposed action should it be implemented....¹⁴

This part of the statute is often referred to as procedural NEPA as it directs federal agencies to undertake a series of procedures, the most significant of

⁹NEPA §102. This language was crucial for Congress to emphasize that the duties imposed by NEPA were not to be avoided except under the most exceptional circumstances. See section II.C., infra.

¹⁰NEPA §102(1).

¹¹NEPA §102(2) (emphasis added).

¹²NEPA §102(2)(a).

¹³NEPA §102(2)(b); see also NEPA §102(2)(d)-(g).

¹⁴NEPA §102(2)(c); codified at 42 U.S.C. §4332(2)(C).

which is the filing of an Environmental Impact Statement (EIS) in conjunction with any major federal action which affects the human environment. The interpretation and extent of these obligations have been the subject of enormous volumes of litigation and continues to be the subject of controversy today.¹⁵ The operation of procedural NEPA will be discussed in more detail below in conjunction with the regulations promulgated by the CEQ.

Section 103 directs that every agency in the federal government create procedures and policies so that the agency may comply with the procedural strictures of NEPA.¹⁶ The regulations promulgated by the FDA have been the subject of controversy as will be discussed below.¹⁷

Title II establishes the President's Council on Environmental Quality (CEQ)¹⁸ which is responsible for submitting an annual Environmental Quality Report to Congress.¹⁹ The Council must carry out similar administrative reporting tasks such as gathering information on environmental trends,²⁰ reviewing federal government programs for compliance with NEPA's substantive goals,²¹ and recommending further policy enhancements to improve environmental quality.²² However, the CEQ's most important functions were created by a series of executive orders which gave the CEQ authority to promulgate NEPA regulations

¹⁵For example, a 1995 survey of major NEPA cases revealed 45 significant decisions handed down by federal District and Circuit courts for that year alone. See William M. Cohen, Fran Moneski, NEPA Court Decision Survey, SA85/3 ALI-ABA 1323 (1996).

¹⁶NEPA §103.

¹⁷See section IV(B), infra.

¹⁸NEPA §202.

¹⁹NEPA §204(1).

²⁰NEPA §204(2).

²¹NEPA §204(3).

²²NEPA §204(4).

to coordinate agency compliance with the statute.²³ This authority resulted in regulations that are designed to enact NEPA's procedural provisions.²⁴ Commentators have noted that while the CEQ's regulations themselves cannot have any substantive effect on decision making, the regulations echo the substantive elements of NEPA's provisions.²⁵ While a detailed understanding of NEPA procedures would be beyond the scope of this paper, a brief discussion of the regulations will help clarify latter discussion.

As noted above, the procedures of section 102(2)(c) are the crucial element of NEPA's mandate. Perhaps a simple method to understand NEPA procedures is to examine the definitions of key terms from §102(2)(c). The statute states the triggering conditions for NEPA procedures are "every recommendation or report on proposals for legislation and other major federal action significantly affecting the quality of the human environment."²⁶ While the first condition of "every recommendation or report on proposals for litigation" is self-explanatory, as well as relatively narrow, the phrase "major federal action" has been the subject of controversy and interpretation.²⁷ However, the CEQ has interpreted "major federal action" broadly to include "actions with effects that may be major and which are potentially subject to Federal control and responsibility."²⁸ This definition categories federal action as including, "adoption of official pol-

icy . . . adoption of formal plans . . . adoption of programs . . . approval of specific

²³Executive Order 11514 (1970) as amended by Executive Order 11991 (1977).

²⁴See 43 Fed. Reg. 55978 (1978) (codified at 40 C.F.R. §1500-1508).

²⁵See Lawrence R. Liebesman, The Council on Environmental Quality's Regulations to Implement the National Environmental Policy Act of 1969, 10 Environmental L. Rep. 50039 (1980).

²⁶NEPA §102(c).

²⁷See e.g., Andrus v. Sierra Club, 442 U.S. 347 (1979).

²⁸40 C.F.R. §1508.18 (1999).

projects.”²⁹ Similarly, the CEQ interprets “human environment” “comprehensively to include the natural and physical environment and the relationship of people with that environment.”³⁰ Thus according to these definitions, and in practice, federal agencies must often abide by §102(c) of NEPA for most actions they undertake. Projects with only economic and social effects are specifically excluded from triggering the preparation of an EIS.³¹ The heart of NEPA process is the EIS itself. An EIS is the detailed written statement that incorporates the elements listed in §102(2)(c) of NEPA.³² Typically, when conducting an action that triggers §102(c), an agency will prepare an Environmental Assessment (EA) before preparing a full blown EIS. An EA is a scaled down version of an EIS that “briefly provide[s] sufficient evidence and analysis for determining whether to prepare an EIS.”³³ If, after preparing an EA, the agency determines that the action will not effect the environment in a significant way, the agency issues a Finding of No Significant Impact (FONSI).³⁴ Only if a FONSI is not issued must the agency proceed to prepare a full EIS.³⁵

B. Brief Overview of NEPA Case Law

The scope, accuracy and implications of EA’s, FONSI’s and EIS’s are the subject of most case law on NEPA. Initially, the issue that most agencies

²⁹Id.

³⁰Id. §1508.14.

³¹Id. For instance, IRS Revenue Rulings do not require the preparation of an EIS, but an Army Corp of Engineers plan to build a dam does.

³²Id. §1508.11.

³³Id. §1508.9.

³⁴Id. §1508.13.

³⁵Id. §1508.12

confronted was that once they had prepared an EIS, the agency was uncertain what influence the document's findings must actually exert over decision-making. The substantive sections of NEPA purport to set a high bar for environmental responsibility, yet, as noted earlier, these provisions are not worded in a way that gives them much legal effect.³⁶ In an important early case, Calvert Cliffs' Coordinating Committee, Inc. v. United States Atomic Energy Commission,³⁷ the court considered the difficult question of how much substance review NEPA procedures require. At issue were regulations promulgated by the Atomic Energy Commission which substantially limited the agency's ability to consider the environmental effects of its actions, even after the preparation of an EIS.³⁸ Judge Skelly Wright's opinion rejected the Commission's rules, stressing that "Congress did not intend the Act to be such a paper tiger."³⁹ The court stated that "NEPA establishes environmental protection as an integral part of the Atomic Energy's Commission's basic mandate. . . . [I]t must itself take the initiative of considering environmental values at every distinctive and comprehensive stage of the process. . . ." ⁴⁰

The Supreme Court did not follow the lower court's invitation to read NEPA as requiring a certain level of substantive review as part of its procedural requirements. In Kleppe v. Sierra Club,⁴¹ the first Supreme Court case to address this issue fully, the Court denied a claim that the Department of Interior had an obli-

³⁶See Bill Lockhart, NEPA: All Form, No Substance?, 14 J. Energy Nat. Resources & Envtl. L. 415 (1994).

³⁷449 F. 2d 1109 (D.C. Cir. 1971).

³⁸Id. at 1116-17.

³⁹Id. at 1114.

⁴⁰Id. at 1119.

⁴¹427 U.S. 390 (1976).

gation to conduct a regional EIS rather than separate EIS for individual coal mining operations in the northern plain states. The Court rejected a balancing test employed by the Court of Appeals to justify the regional EIS, holding that “[a] court has no authority to depart from the statutory language and, by balancing of court-devised factors, determine a point during the germination process . . . at which an impact statement should be prepared.”⁴² The Court furthered emphasized this principle in Vermont Yankee Nuclear Power Corp. v. Natural Resources Defense Council, stating, “NEPA does set forth significant substantive goals for the Nation, but its mandate to the agencies is essentially procedural.”⁴³ Thus NEPA’s procedural mandate remains a vital obligation of everyday agency action while the extent of the statute’s substantive component remains the subject of academic discussion and litigation.⁴⁴ Extensive litigation has formalized many of the other elements of NEPA’s procedural requirements.⁴⁵

An appreciation of the substance/procedure debate about NEPA is a necessary backdrop to consider how beholden the FDA should be to the statute. The case law demonstrates that courts have been left to fill in some gaps in the statute – most importantly the balance between procedural and substantive obligations under NEPA. There is no construction of these requirements, however, that

⁴²Id. at 406.

⁴³435 U.S. 519, 558 (1978).

⁴⁴For an argument that NEPA does give federal agencies the authority to make substantive environmental decision that otherwise would not be authorized by their organic statutes, see Lockhart, supra.

⁴⁵See e.g., Lujan v. National Wildlife Federation, 497 U.S. 871 (1990) (refining standing doctrine for NEPA suits); Robertson v. Methow Valley Citizens Council, 490 U.S. 332 (1989) (defining the necessary extent of NEPA analysis); Marsh v. Oregon Resources Council, 490 U.S. 360 (1989) (holding that arbitrary and capricious review applies to NEPA-mandated EIS); Andrus v. Sierra Club, 442 U.S. 347 (1979) (defining the extent of what constitutes major federal action)

would categorically exempt the FDA from considering the effects of its actions on the human environment.

C. Overview of the Legislative History of NEPA

The final element in this brief tour of NEPA is to examine the legislative history of the statute to see if it sheds any light on whether Congress was concerned at all with the environmental effects of the regulation of foods and drugs in enacting NEPA. That is, does the legislative history contain any indication that Congress was specifically worried about food safety, or human health, when it enacted NEPA, or was Congress focusing more broadly on the environment in general? Not surprisingly, the answer to this question appears to be that Congress did not consider how the subject matter regulated by each agency could effect the environment when enacting NEPA.

Given the sweeping nature of the NEPA statute, its legislative history yields few clues as to the specifics of Congressional intent.⁴⁶ As an initial explanation, it is interesting to note the original House Bill did not even contain the “action-forcing” statutes of Title I, thus the House Committee reports do not discuss the meaning of most of the actual legislation.⁴⁷ The Conference reports and

Congressional Records, however, document Congress’ commitment that NEPA

⁴⁶Many treatises include a great deal of information on NEPA’s legislative history. See e.g., Frank P. Grad, Treatise on Environmental Law, New York, M. Bender, 1999; Erica L. Dolgin, Federal Environmental Law, St. Paul, West Pub. Co. (1974).

⁴⁷Before conference the House passed H.R. 12549, 91st Cong. (1969), which only addressed the creation of the CEQ. See also 115 Cong. Rec. 26572, 26582-3 (1969) (statement of Representative Daddario).

should apply to all agencies and that there should be no loopholes for compliance. The conference report indicates that the statutory language that opens §102(c) – “to the fullest extent possible” – should “make clear that each agency of the federal government shall comply with the directives unless existing law expressly prohibits or makes full compliance impossible.”⁴⁸ The report emphasizes that the phrase “to the fullest extent possible” shall not be used to avoid compliance with §102 nor shall an agency use an excessively narrow construction of its organic statute to avoid compliance with NEPA.⁴⁹

Furthermore, there are indications that the substantive components of NEPA, though lacking in legal force, was nevertheless important to Congress’ design. The phrase “fullest extent possible” was placed at the beginning of §102 so as to apply to both the policy elements of §102(a)-(b) and (d)-(g) as well as the procedural requirements of §102(c).⁵⁰ The Senate on Interior and Insular Affairs Committee Report accompanying the original Senate version of NEPA⁵¹ stressed that the statute was written to “provide all agencies with a legislative mandate and a responsibility to consider the consequences of their actions on the environment” throughout the decision making process.⁵² Certainly, this legislative history indicates that while the decision-making process of the FDA should implicate NEPA procedures and substantive guidelines, there is no indication that Congress intended to deal with particular environmental effects of

⁴⁸H.R. Rep. No. 91-765 (1969) (reprinted in 1969 U.S.C.C.A.N. 2751, 2768).

⁴⁹Id.

⁵⁰115 Cong. Rec. 40,418 (1969).

⁵¹S. 1075, 91st Cong. (1969).

⁵²S. Rep. No. 91-296 at 14, (1969) (emphasis added).

FDA actions and programs.

III. the scope of the fda and its impact on the environment

A. Overview of the Food and Drug Administration

The scope of the jurisdiction of the Food and Drug Administration (FDA) is enormous. It is estimated that 25 cents of every dollar spent in America goes towards a product regulated by the FDA.⁵³ The Federal Food and Drug Act was first enacted in 1906,⁵⁴ though the current statutes originated from the 1938 Federal Food, Drug, and Cosmetic Act (FDCA).⁵⁵ Since then the statute has been amended dozens of times with the most recent revisions in the Modernization Act of 1997.⁵⁶ Some form of the Food and Drug Administration has existed, under various names and different departments since 1862.⁵⁷ The purpose of this section is not to describe the extensive history or institutional structure of the FDA and the FDCA, but rather to sketch out the various realms of jurisdiction for which the agency has responsibility. At first glance, it might not seem intuitive that decision making concerning these subject matters could effect the environment. In fact, decisions in many areas of the FDA's jurisdiction have a potentially profound environmental impact. As this section will demonstrate, the FDA's organic statutes do not include any latitude to

⁵³Lecture notes, Peter Barton Hutt, January 4, 1999.

⁵⁴Pub. L. No. 59-384, 34 Stat. 768 (1906).

⁵⁵52 Stat. 1040 (1938), codified at 21 U.S.C. §301 et. seq. (1999).

⁵⁶Pub. L. No. 105-115, 111 Stat. 2296 (1997).

⁵⁷See Peter B. Hutt, A Historical Introduction, 45 Food Drug Cosm. L. J. 17 (1990).

consider environmental effects of the agency's decisions. Thus the burden falls entirely on NEPA to ensure the agency considers the effects of its decisions beyond health and safety. An understanding of how the FDA regulates the various areas of its jurisdiction is necessary to appreciate the importance of the relationship between NEPA and the FDA.

B. Principle Areas of the FDA's Jurisdiction.

One of the FDA's primary concerns is ensuring that food consumed by Americans is correctly labelled and unadulterated. The FDCA contains lengthy definitions of these terms,⁵⁸ which include everything from how nutritional information must be presented⁵⁹ to the safety requirements for dietary supplements.⁶⁰ The FDA enforces these complex definitions by prohibiting the introduction into interstate commerce of misbranded or adulterated foods.⁶¹ The clear focus of these rules is to ensure that the food that reaches Americans tables is safe for consumption⁶² and that is properly labeled as to contents,⁶³ quantity,⁶⁴ etc. However, under these guidelines it is entirely possible for foods that meet the FDA's criteria for safety and branding to have the potential to cause environmental harm, in their production or growth. Genetically engineered food such

⁵⁸21 U.S.C. §342 (definition of adulterated food); 21 U.S.C. §343 (definition of misbranded food).

⁵⁹21 U.S.C. §343(q).

⁶⁰21 U.S.C. §342(f).

⁶¹21 U.S.C. §331(a) (misbranding); 21 U.S.C. §331(b) (adulteration).

⁶²See 21 U.S.C. §342(a)(1) (definition of poisonous and unsanitary ingredients).

⁶³See e.g., 21 U.S.C. §343(k) (requiring labeling of artificial flavoring, coloring, or preservatives).

⁶⁴See 21 U.S.C. §343(e)(2) (requiring quantity information on any packaged foods).

as Bt Corn presents one such case.⁶⁵

The regulation of drugs and medical devices is the other bulwark of the FDA's responsibility. The FDCA employs the same mechanism of prohibiting adulteration and misbranding as the primary means for regulating drugs.⁶⁶ However, the statutes add another requirement, which is that no drug may be introduced into interstate commerce unless an application for a new drug is approved by the FDA.⁶⁷ These petitions, termed new drug applications (NDAs), are the mechanism by which the FDA reviews drugs for safety and effectiveness.⁶⁸ Before a manufacturer can even file an NDA, the product must be tested, first on animals and then on humans. But to conduct this testing the drug must typically travel through interstate commerce to reach researchers at various institutions. Thus the FDCA creates an exemption to allow these drugs into interstate commerce for the purpose of investigation.⁶⁹ This process, which the FDA oversees and regulates, is known as the Investigational New Drug (IND) phase. The FDA procedures for INDs and for NDAs do not consider questions external to the effect on humans of the drug, such as where it comes from, how it is extracted, and the sustainability of the resource. For the most part these concerns are of no consequence since drug materials are either synthetic or derived from a common substances. The experience of the approval of taxol, a cancer fighting drug derived from the Pacific Yew tree, however, demonstrates how the approval of

⁶⁵See section IV(F), *infra*.

⁶⁶21 U.S.C. §351 (adulterated drugs and devices), 21 U.S.C. §352 (misbranded drugs and devices).

⁶⁷21 U.S.C. §355(a).

⁶⁸21 U.S.C. §355(b)(1)(A).

⁶⁹21 U.S.C. §355(i).

an NDA can have drastic environmental consequences.⁷⁰

There are several other areas of the FDA's authority that present similar problems. For example, in addition to regulating drugs for human use, the FDA is also in charge of regulating new animal drugs and animal feed.⁷¹ As expected, the FDA is principally concerned with the safety and efficacy of those drugs on the target animal, as well as any effects passed on to humans through the consumption of those animals.⁷² The controversy over the approval of Recombinant Bovine Somatotropin (rbST) demonstrates the clash between emerging genetic technologies and fears that these technologies could harm the environment.⁷³ Furthermore, even seemingly innocuous areas of the FDA's jurisdiction, such as medical devices, may present environmental concerns. For instance, it seems that part of the concern in enacting certain provisions of the Modernization Act of 1997 was a potential clash with the EPA over the regulation of metered dose inhalers (asthma inhalers).⁷⁴ While the FDA has the incredible responsibility of ensuring the safety for a mass of products that for the most part do not involve environmental concerns, there is a discrete subset of cases which involve the potential for environmental impact.⁷⁵ It is in this area that the interaction between the FDA and NEPA becomes particularly relevant. Part IV of this paper will examine this interaction in detail.

⁷⁰See section IV(C), *infra*.

⁷¹21 U.S.C. §360b.

⁷²21 U.S.C. §360b (d)(2).

⁷³See section IV(D), *infra*.

⁷⁴See section IV(E), *infra* (controversy surrounding the chlorofluorocarbons (CFCs) used as propellant in these devices).

⁷⁵As its name implies the FDCA also contains rules for cosmetics similar to those for food and drugs. See 21 U.S.C. §361-63. However, and perhaps not surprisingly, there is little concern that the regulation of the cosmetic industry has the potential to have any real environmental impact.

iv. the interaction of the fda with nepa – an historical approach

Within a few years of the passage of NEPA, the FDA confronted the first in a series of rounds of interaction with NEPA as the agency struggled to find the balance between complying with the statutory mandate of NEPA and fulfilling the agency's own organic mandate. The interaction between the FDA and NEPA is a long and ongoing one. Several times the agency has promulgated and revised regulations to comply with NEPA. Those regulations have been challenged in court. Other actions taken by the FDA such as the approval of drugs or drug testing have been criticized or challenged in court. Even a Presidential initiative enacting the Vice President's National Performance Review addressed the issue of the extent of the interaction between the FDA and NEPA. Today the fundamental questions – how much should the regulation of food and drugs focus on the external environmental effects of those products and to what extent is NEPA the proper vehicle for enforcing that focus – remain unanswered. The increasing prominence of the products of biotechnology in our food and drug supply have only continued to highlight these issues. In one sense, the interaction between the FDA and NEPA is merely a microcosm for a larger regulatory problem revolving around the coordination of agencies and statutes to regulate biotechnology. Also the FDA's various attempts to either comply with or evade NEPA emphasize the inherent tension in NEPA itself between its procedural mandates and its substantive goals. The FDA does conduct EAs and

occasionally EISs – but what the agency continues to grapple with is the degree to which the agency’s decision-making must actually reflect the results in those documents. To understand the evolution of the relationship between the FDA and NEPA, the paper progresses historically through rounds of controversies between the agency and the statute.

A. Round 1: EDF v. Mathews

The FDA’s first attempt to address the requirements of NEPA came 3 years after the statute’s passage. The FDA promulgated regulations establishing procedures for preparation of environmental impact statements for major agency actions significantly affecting the environment.⁷⁶ While these initial regulations were themselves unremarkable, two years later the FDA issued its legal interpretation of these regulations. In this interpretation, the FDA addressed one of the fundamental questions head on by challenging the extent to which the agency must take or refrain from action based on an adverse EIS to a proposed action. A suit challenging the FDA’s regulatory interpretation forced a court to outline the extent to which an EIS must influence the FDA’s decision making.

The issue arose in the context of the FDA’s approval of the use of plastic bottles to package foods and soft drinks.⁷⁷ In keeping with NEPA and the reg-

⁷⁶21 C.F.R. Part 6 (1974), published in 38 Fed. Reg. 7001 (1973).

⁷⁷The FDA has the authority to regulate the packaging of food based in part on 21 U.S.C. §342(a)(6) which defines food as adulterated “if its container is composed, in whole or in part, of any poisonous or deleterious substance which may be render the contents injurious to health,” and in part on 21 U.S.C. §321(s) which includes in the definition of “food additive” any substance “intended for use in producing, manufacturing,... packaging, transporting, or

ulations promulgated by the FDA, the agency prepared an EIS studying the environmental effects of the plastic bottles on the environment.⁷⁸ The result of the EIS indicated several adverse environmental effect of the plastic bottles, but with no threat to human or safety from the plastic bottles identified, the FDA was hesitant to refrain from approving the bottles.⁷⁹ On the same day that the EIS was published, the FDA issued a regulation interpreting its authority to act under NEPA which the FDA gave immediate applicability – including the results of the plastic bottle EIS.⁸⁰ In brief, the regulation announced the FDA’s legal interpretation that an adverse EIS does not permit the FDA to act if the adverse impact identified does not involve a threat to public health, adulteration, or misbranding or some other factor already identified by the FDCA.⁸¹ The regulation states: “Although adverse environmental impacts relating to destruction of scenic beauty, depletion of energy resources, increase in litter and trash.. are not condoned by the Commissioner [of the FDA], he has no legal authority to prevent them.”⁸² The agency implemented the ruling immediately as final agency action since the interpretation falls outside the scope of notice and comment rulemaking.⁸³ However, the agency almost invited a legal challenge to the regulation stating “[i]t is the Commissioner’s opinion that . . . any person [in this country] has standing to obtain judicial review of this regulation . . .”⁸⁴

holding food.” Such substances must be evaluated scientifically for their safety before they can be used. Id.

⁷⁸NEPA §102(2)(c), 21 C.F.R. Part 6 (1974).

⁷⁹See Comment, NEPA’s Power to Amend Other Federal Laws: EDF Seeks to Compel the FDA to Consider Environment
5 Env’tl. L. Rep. 10104 (1975).

⁸⁰See id.

⁸¹Legal Effect of NEPA on Agency Action, 40 Fed. Reg. 16662-63 (1975).

⁸²Id.

⁸³Id.

⁸⁴Id.

The regulation contained a detailed justification for this determination. The legal underpinning of the FDA’s argument was that the FDCA prescribes specific criteria by which the agency may approve or deny the various applications and petitions for which the agency has responsibility.⁸⁵ While NEPA requires the FDA to prepare EISs, which may or may not reveal adverse effects of agency action, NEPA “does not contain independent substantive legal authority permitting or requiring the Commissioner to take or refrain from taking any particular action on the basis of a determination of an adverse environmental impact.”⁸⁶ The FDA based its regulation on the Supreme Court’s holding in United States v. Students Challenging Regulatory Agency Procedures (SCRAP I) that Congress did not intend NEPA to repeal by implication any other federal statute.⁸⁷ The FDA believed that taking action based on the result of an adverse EIS where no organic statutory justification existed for that action would implicitly reject the organic statute. Thus unless the FDCA (or some others statute administered by the FDA) itself prohibits the environmental impact identified by the EIS, the FDA may not act on the basis of the EIS alone.⁸⁸ The justification of the FDA is flawed for several reasons. First, its reliance on the rationale in SCRAP I is dubious because of the factual setting of that case. SCRAP I was a suit by environmentalists challenging railroad rates that placed a surcharge on recycled materials.⁸⁹ The lower court granted the environmentalists petition and enforced its holding by issuing an injunction against

⁸⁵See Section III(B), *supra*.

⁸⁶40 Fed. Reg. 16662.

⁸⁷412 U.S. 669, 694 (1973).

⁸⁸40 Fed. Reg. 16662.

⁸⁹412 U.S. at 677.

the Interstate Commerce Commission (ICC) to suspend the rates.⁹⁰ At issue in the case was the court's power to issue the injunction, not the ICC's power to take substantive action based on NEPA. The Supreme Court had previously held in Arrow Transportation Co. v. Southern Railway Co.⁹¹ that Congress, in 49 U.S.C. §15(7), had explicitly eliminated judicial power to issue injunctions concerning railroad rates against the ICC. To allow a court to issue an injunction in this case based on NEPA would explicitly contradict Arrow and 49 U.S.C. section 15(7). The Court refused to read NEPA as implicitly repealing section 15(7).⁹² However, there is no such link between the FDA's actions and NEPA. No statute explicitly forbids the FDA from taking or refraining from taking action based on an adverse EIS. The FDA's attempt to read its own organic statute in this manner seems strained at best. There is a qualitative difference between using NEPA to circumvent an explicit limitation on judicial power and allowing NEPA to inform a broad class of decision making.

The FDA's narrow reading of its own statute as binding the agency to utilize only statutorily mandated factors such as public health, adulteration, and misbranding in decision making is problematic. As discussed above, the legislative history of NEPA indicates a clear intent to empower agencies to make decision based on environmental criteria.⁹³ Recall that the House conferees in their report explicitly stated their intent that an agency should not use an excessively narrow construction of its organic statute to avoid compliance with NEPA.⁹⁴

⁹⁰346 F. Supp. 189 (1972)

⁹¹372 U.S. 658, 667 (1963).

⁹²412 U.S. at 694.

⁹³See Section II(C), supra.

⁹⁴See note 49, supra.

Additionally, the FDA's reading of the FDCA potentially conflicts with that of its parent agency, at that time, Health and Education and Welfare (HEW).⁹⁵ In complying with Section 103 of NEPA, HEW issued a report on the status of its agencies compliance with NEPA.⁹⁶ The report states that "a review of the authorizing legislation does not reveal any program in which we may not impose appropriate conditions intended to effect compliance with the purpose and provisions of [NEPA] ... The applicable authorizing statutes provide, in vary terms, for the imposition of terms and conditions. This is not construed as prohibiting the implementation of policies and procedures directed at avoiding adverse environmental effects."⁹⁷ While the full implications of that report on the FDA are not clear, it cast doubt on the value of the FDA's interpretation. In fact, one article written at the time suggested that the regulation was motivated by the FDA's uncertainty on the issue and the agency was counting on a court decision to clarify the agency's legal relationship to NEPA.⁹⁸ That decision came in the form of suit brought by the Environmental Defense Fund (EDF) challenging the regulation for violating NEPA. In EDF, Inc. v. Mathews, the district court for the District of Columbia held that the regulation violated NEPA.⁹⁹ The decision relied heavily on Calvert Cliffs for the prospect that federal agencies are compelled by NEPA to take environmental values into con-

⁹⁵See 5 Env'tl. L. Rep. 10104, note 79 *supra*.

⁹⁶NEPA §103, 42 U.S.C. 4335 (1999) requires agencies to "review their present statutory authority ... for the purpose of determining whether there are any deficiencies or inconsistencies therein which prohibit full compliance with the purposes and provisions of this Act ..."

⁹⁷Committee on Merchant Marine and Fisheries, Administration of the National Environmental Policy Act, Part II, 816, House of Representatives, 91st Congress, 2nd Session, Dec. 1970, Serial No. 91-41 cited in 5 Env'tl. L. Rep. 10104, note 79 *supra*.

⁹⁸5 Env'tl. L. Rep. 10104, note 79 *supra*.

⁹⁹410 F. Supp. 336 (D.D.C. 1976).

sideration.¹⁰⁰ The court tersely concludes, “we find that NEPA provides the FDA with supplementary authority to base its substantive decisions on all environmental considerations including those not expressly identified in the FDCA and the FDA’s other statutes.”¹⁰¹ The court purports to base its decision in the legislative history, the statutory language, the holdings of the other courts, and the constructions adopted by other federal agencies without actually expounding those explanations.¹⁰² Addressing the issue of the extent of NEPA’s substantive power to effect agency decisions, the court quoted from Calvert Cliffs, “what possible purpose could there be in requiring the ‘detailed statement’ to be before the hearing boards if the boards are free to ignore entirely the contents of the statement? NEPA was meant to do more than regulate the flow of papers in the federal bureaucracy.”¹⁰³

Thus the first major interaction between the FDA and NEPA added to the continuing challenge to define the boundaries of NEPA’s substantive power. The decision of the district court was not appealed and the regulation was, therefore, revoked.

B. Round 2: Implementing Regulations to Comply with NEPA

In 1985, the FDA conducted a significant revision of its regulations previously promulgated to comply with NEPA. The regulations are quite specific –

¹⁰⁰Id. at 337.

¹⁰¹Id. at 338.

¹⁰²Id.

¹⁰³Id. at 339 (quoting Calvert Cliffs, 449 F.2d at 117).

they address the details of when EA's and EIS should be prepared, how these documents should be prepared, and what actions are categorically excluded from requiring any NEPA analysis.¹⁰⁴ The promulgation of the new final rules in 1985 were accompanied by an extensive document addressing many of the comments made to the agency during the public comment period of the "notice and comment rulemaking" procedure.¹⁰⁵ The tone of the FDA's response to the comments indicates that the lesson of EDF v. Mathews was well-heeded and the FDA recognized its responsibility to conduct environmental investigations whenever the potential existed for agency action to affect the environment. These new regulations also benefited from considerably more guidance from the CEQ as was previously available since it was not until 1978 that the CEQ promulgating its regulations to coordinate compliance with NEPA.¹⁰⁶ Though the precise contours of the FDA regulations are not particularly instructive, three areas of the regulations deserve focus. Those areas are when the FDA will conduct EAs, when it will conduct EISs, and what subject matter it categorically excludes from consideration.

As a preliminary matter the FDA took deliberate steps to recognize the authority and importance of NEPA. For instance, the regulations begin with a statement of purpose that recognizes NEPA as the "national charter for protection, restoration, and enhancement of the environment."¹⁰⁷ The FDA recognized that as a matter of policy, the agency's programs will be planned, developed,

¹⁰⁴21 C.F.R. Part 25 (1986).

¹⁰⁵NEPA, Policies and Procedures, 50 Fed. Reg. 16636 (1985).

¹⁰⁶43 Fed. Reg. 56003 (Nov. 29, 1978) codified in 40 C.F.R. Part 1508.

¹⁰⁷21 C.F.R. §25.1 (1986).

and executed in a manner so as to “achieve the policies declared by NEPA and required by the CEQ regulations to ensure responsible stewardship of the environment for present and future generations.”¹⁰⁸ The regulations emphasize that NEPA planning is an integral part of the regulatory process and that the NEPA process is initiated either when the agency begins action under its own statutory authority or when an applicant or petitioner brings an action to the FDA.¹⁰⁹ The agency was also motivated by a desire to streamline the process and reduce costs associated with NEPA while still remaining vigilant to adverse environmental impacts.¹¹⁰

The FDA recognized that most of its actions will require the threshold determination of environmental impact made by an EA. The regulations identify 19 categories of agency action that typically require the preparation of an EA.¹¹¹ Among those requirements are major recommendations or reports made to Congress,¹¹² research supported by contracts or grants,¹¹³ establishment of labeling requirements,¹¹⁴ amendments to FDA regulations,¹¹⁵ affirmation of a food substance as generally recognized as safe,¹¹⁶ approval of NDAs and INDs,¹¹⁷ and approval new animal drug applications.¹¹⁸ Note that not all EAs must be prepared by the FDA itself. When one of the above actions are

¹⁰⁸Id. at §25.5.

¹⁰⁹Id. at §25.10.

¹¹⁰50 Fed. Reg. 16636.

¹¹¹Id. at §25.22.

¹¹²Id. at §25.22(a)(1).

¹¹³Id. at §25.22(a)(5).

¹¹⁴Id. at §25.22(a)(6).

¹¹⁵Id. at §25.22(a)(7).

¹¹⁶Id. at §25.22(a)(12).

¹¹⁷Id. at §25.22(a)(14).

¹¹⁸Id. at §25.22(a)(17).

requested by an applicant or petitioner, it is that person that must prepare the EA.¹¹⁹ However, the FDA remains responsible for ensuring that the EAs are accurate and for interpreting the results (i.e. whether to proceed with an EIS or issue a FONSI).¹²⁰ In promulgating these categories of actions requiring an EA, the FDA rejected comments that suggested that many of these areas are ones which could be categorically excluded from preparation of an EA.¹²¹ Most of these comments were directed at exempting the various forms of drug applications and were likely from interested parties such as the drug manufacturers themselves seeking to expedite their own processes. The FDA responded to these comments by emphasizing that in its experience these actions, such as NDAs, in fact often require an EA.¹²² The true test of this statement was born out in later controversies over such types of FDA action.¹²³

In determining which types of agency action require the preparation of a complete EIS, the FDA was more terse. Section 25.22 states, “There are no categories of agency actions which routinely significantly affect the quality of the human environment and which therefore ordinarily require the preparation of an EIS.”¹²⁴ Of course, the agency’s regulation requires preparation of an EIS when an EA leads to a finding that an action may impact the environment¹²⁵ or when an agency official believes that an action under consideration may significantly

¹¹⁹Id. at §25.22(b).

¹²⁰Id. at §25.22(d).

¹²¹50 Fed. Reg. 16636.

¹²²Id.

¹²³See section IV(C), (D), infra.

¹²⁴21 C.F.R. §25.22(a) (1986). This regulation, along with most of Part 25 of Title 21 of the C.F.R., remains in effect today (though some subsection number have changed). See 21 C.F.R. §25.22(a) (1999).

¹²⁵21 C.F.R. §25.22(b)(1).

affect the environment.¹²⁶ The FDA justified this regulation by stating that it could not identify any classes of actions which would routinely require an EIS so instead the agency left the determination to a case-by-case evaluation of EAs.¹²⁷ Given the discussion of the areas of jurisdiction of the FDA discussed above, this conclusion appears reasonable because the majority of FDA decisions have no environmental impact. Furthermore, the regulation was surely motivated, in part, by a desire not to impose on all applicants and petitioners before the FDA the requirement of preparing a full EIS where an EA would suffice, at least initially, to assess the potential harm of their actions.

The third major category of actions which the FDA identified were those that did not require any form environmental assessment. The CEQ regulations carve out an exception from the normal requirements of NEPA for “categorical exclusions.” A categorical exclusion is a category of major federal action that “do[es] not individually or cumulatively have a significant effect on the environment.”¹²⁸ Any agency creating categorical exclusions must identify specific criteria to explain why those actions do not require any environmental analysis.¹²⁹ The FDA regulations identify several dozen categorical exclusions which touch on most areas of the FDA’s jurisdiction.¹³⁰ The specific categorical exclu-

¹²⁶Id. at §25.22(b)(2).

¹²⁷50 Fed. Reg. 16636.

¹²⁸40 C.F.R. §1508.4 (1999).

¹²⁹Id. at §1507.3(b)(2).

¹³⁰For example, 21 C.F.R. §25.24(a) (general areas such as routine administrative actions, maintenance of FDA facilities, enforcement actions, and promulgation of laboratory procedures); id. at §25.24(b) (food areas such as testing batches of color additives and promulgating interim food additive regulation); id. at §25.24(c) (drugs and biologics such as amending a NDA under certain conditions, testing batches of antibiotics, and certain INDs where all waste will be controlled or non-toxic); id. at §25.24(d) (animal drugs); id. at §25.24(e) (devices and medical products).

sions do not cover areas which are particularly controversial.¹³¹ The categorical exclusions themselves are broken into a few classes of justification for their status as categorical exclusions. The FDA defends one of those classes as meriting categorical exclusion because the actions involved “will not result in the production or distribution of any substance, and therefore will not result in the introduction of any substance into the environment.”¹³² This justification is noteworthy because it is entirely output oriented. The FDA, throughout its listing of categorical exclusions, exempts actions that will not produce harmful by-products. But the FDA does not consider the possibility that these actions may have environmental affects before production – i.e. input oriented.¹³³

With this background on how the FDA actually implements NEPA, the paper will examine several more recent interactions of the agency and the statute in the confusing era of genetic technology and governmental modernization. The next section will demonstrate that occasionally the inputs in the process are those that impact the environment.

C. Round 3: The Pacific Yew and the Taxol Controversy

The interaction between the FDA and NEPA is inevitably complicated by the involvement of other federal agencies in a particular action. The experience

¹³¹E.g. it is difficult to argue that the replacement of window on a facility controlled by the FDA warrants an EA. See 21 C.F.R. §25.24(a)(12)(i).

¹³²21 C.F.R. §25.24.

¹³³Certainly, this is not intended as a stinging criticism since the FDA can override the categorical exclusion of any particular action should the FDA believe the action may significantly affect the environment. See 21 C.F.R. §25.23(b). However, as a structural point, it highlights the focus and attention of the agency.

of the development of the cancer drug taxol from the Pacific Yew tree engaged the FDA in a process that involved the National Forest Service, the Bureau of Land Management (BLM), the National Cancer Institute (NCI), as well as private industry. The challenge of developing a potentially life-saving drug implicated various areas of each agency's expertise and jurisdiction and yet the environmental impact from all these agencies actions involved the same concern – the depletion of the Pacific Yew tree. The experience of the FDA with the Pacific Yew was not one that required litigation or legislation to resolve. Ultimately, the agencies coordinated their efforts to produce an EIS that hopefully informed at least the FDA's decision making. The story of taxol is useful because it outlines the complexities of administering NEPA in a multi-agency setting and demonstrates how the FDA responded to that challenge.

The Pacific Yew tree is an essential yet non-dominant component of the old growth forests of the Pacific Northwest.¹³⁴ The tree ranges from southern Alaska down to central California and east to northern Idaho and Montana. However, the yew only occurs in approximately 2.5 million acres of the 85 million acres of commercial forest in the Pacific Northwest forests in the lower 48 states. Satellite imagery estimates that there are approximately 130 million yew

trees in Oregon and Washington on Forest Service Land.¹³⁵

¹³⁴See Douglas O. Heiken, The Pacific Yew and Taxol: Federal Management of an Emerging Resource, 7 J. Envtl. L. and Litig. 175 (1992). The following discussion (section IV(C)) draws almost exclusively from this article which was the most comprehensive on the subject. I do not wish to give the impression that I have done the original research on this issue. Rather than cite every fact in this section to this article, I will highlight the original documents, which I have examined, that are particularly relevant to this subject. Summarizing Heiken's article is still useful because I have extracted from it principally the experience of the FDA in managing the resource according to the NEPA's procedures.

¹³⁵See Heiken, supra note 134, at 179-85.

As early as 1967, the National Cancer Institute (NCI) discovered that an extract from the bark of the yew, called taxol, was effective in fighting cancer. By 1991, the substance was in late phase clinical trials for ovarian and breast cancer. NCI and Bristol-Myers Squibb entered into an agreement to coordinate research on taxol.¹³⁶ The FDA was involved in these procedures in approving the IND that regulates clinical trials on human beings.¹³⁷ While the discussion above emphasized that the FDA only considers the health and safety effects of the potential drug on human beings,¹³⁸ in the case of taxol there is enormous externality to that limitation. That externality is the fact that taxol's primary (and currently only) source is yew tree bark. Before 1991, approximately 200,000 pounds of bark had been harvested from the forests of Washington and Oregon for drug investigation purposes. But when taxol entered the more advanced phases of research the NCI and Bristol-Myers estimated needing 750,000 pounds of bark annually and, in fact, the harvest in 1991 was estimated at 825,000 pounds. Heiken estimates that to supply this quantity of yew bark would require approximately 95,000 mature, harvestable yew trees annually.¹³⁹

The bulk of the responsibility for managing this resource belongs with the Forest Service or the BLM, on whose land the yew trees grow, and so the NCI and

¹³⁶Opportunity for a Cooperative Research and Development Agreement for the Scientific and Commercial Development of Taxol, 54 Fed. Reg. 31733 (1989).

¹³⁷See 21 C.F.R. §312.40 (1999) which sets out the procedures by which an investigational new drug may be used in a clinical trial; 21 C.F.R. §312.21 regulates the phases of clinical trials once an IND has been approved. The first phase involves laboratory testing of the drug. Phases II and III involve clinical trials on humans which increase scope and size.

¹³⁸See Section III(B), *supra*.

¹³⁹While this may seem meager compared to the 130 million tree population estimate, it is far more daunting when taken in context with evidence that most of these trees are either too old or too young to harvest and that it takes between 14-50 years for a yew to add one inch of diameter (harvestable trees are about 10 inches in diameter). See Heiken, *supra* note 134, at 189-92.

Bristol-Myers must seek these agencies approval to harvest the trees. However, each approval of an IND by the FDA makes this harvesting possible. Furthermore, should researchers develop any alternatives to yew bark as a source for taxol, the FDA would need to approve those alternatives through an IND before clinical study could begin. Heikin emphasizes that NEPA should have been the vehicle for informing decision making by FDA (and the other federal agencies) to examine these problems. Yet the FDA never prepared an EIS in conjunction with the IND for taxol from yew bark.¹⁴⁰ Neither the NCI nor Bristol Meyer submitted an EA in conjunction with their IND, but the FDA's own regulations place some responsibility on itself to identify those situations where an EIS would be necessary. Certainly, a proposed drug investigation that calls for the removal of 750,000 pounds of bark from a single tree species "may significantly affect the quality of the human environment." The blame lies not solely with the FDA – until 1991 no federal agency even agreed to prepare an EIS in conjunction with taxol.¹⁴¹ Nevertheless, despite the early failings of these agencies to prepare an EIS, the process eventually got underway.

The FDA's role in the EIS was as a cooperating agency. The scope of the EIS was much more within the realm of expertise of the Forest Service, but by acting as a cooperating agency, the FDA would be able to incorporate by reference the

findings of the EIS as well as contribute in any useful manner. At the time of

¹⁴⁰Recall that most INDs are subject to categorical exclusion under 21 C.F.R. §25.24(c)(4). However, arguably the exception to this rule found at §25.23(b) that overrides the categorical exclusion if the proposed action would significantly impact the environment should have been applied. Furthermore, at the very least each IND application must include a "claim for categorical exclusion . . . or an EA," *id.* §312.23(a)(7)(iv)(e). Heiken asserts that no environmental documentation accompanied the INDs.

¹⁴¹The Forest Service issued a revised notice of intent to prepare an EIS on the Pacific yew harvest in early 1992. *See* 57 Fed. Reg. 5245 (Feb. 13, 1992).

the publication of Heiken's article the EIS had not yet been published but he criticizes the alternatives under consideration at the time by the agencies.¹⁴² The alternatives proposed at the time dealt with various methods and amounts of actual harvest of the yew – none of these alternative are policy choices within the jurisdiction of the FDA. Heiken states that there were alternatives involving deriving taxol from sources other than yew bark, such as the yew needles or partial synthesis, that should have been addressed as part of the discussion of alternatives mandated by NEPA. Because these alternative sources would have required INDs they would have empowered the FDA to contribute meaningfully to the decision making process.¹⁴³

Despite the obvious failings of the FDA and other federal agencies to follow NEPA procedures for a project with serious environmental consequences, no suit was brought in conjunction with these agency actions. The EIS prepared by the Forest Service was released in November of 1993.¹⁴⁴ The FDA began to follow NEPA procedures when it issued a FONSI for EAs received in conjunction with a NDA for taxol.¹⁴⁵ Several years later, the FDA issued a notice that required all applications for NDAs or INDs involving taxol to prepare EAs which must identify the sources of the Pacific yew that will be harvested to supply the taxol.¹⁴⁶

¹⁴²Among the requirements of an EIS, 40 C.F.R. §1502.14 (1999) includes, “a presentation, in comparative form, of the environmental impacts of the proposal and all reasonable alternatives; the agency preferred alternative; a no-action alternative; and appropriate mitigation measures” (emphasis added).

¹⁴³See Heiken, *supra* note 134, at 191-95, 227-29.

¹⁴⁴See Notice: EIS Availability, 58 Fed. Reg. 52485 (1993).

¹⁴⁵Taxol, EAs and FONSI, 58 Fed. Reg. 3954 (1993).

¹⁴⁶Paclitaxel Drug Products, Environmental Information Needed in New Drug Applications, Abbreviated New Drug Applications, 61 Fed. Reg. 58694 (1996).

The experience of the FDA with taxol demonstrates how slowly it can take agencies to respond to new circumstances. The FDA was unfamiliar with the concept that the development of a drug could impact the environment. But NEPA eventually was heeded and did its job – the Forest Service prepared an EIS which could be referenced by the involved agencies and the FDA now requires any action involving the Pacific yew to include an EA. The interaction between NEPA and the FDA with taxol was ultimately a success in so far as the process eventually worked to protect the yew tree, but whether the FDA adjusted its institutional thinking to acknowledge that drug innovations can impact the environment is less certain.

D. Round 4: Stuaber v. Shalala and the Controversy Over rbST

The next significant interaction between the FDA and NEPA arose over the FDA's controversial approval of recombinant bovine somatotropin (rbST) – a genetically engineered cow hormone that increases milk production. A lawsuit again forced a court to evaluate whether the agency had fulfilled its obligations under NEPA. The controversy over rbST, however, is not primarily a conflict between the FDA and NEPA. Rather, the controversy involves the much broader question of how various agencies should regulate biotechnological products and how to balance the potential risks and benefits of these technologies. As the first major agricultural product created by biotechnology, rbST has been the focus of a great deal of research, criticism, and concern. Use of the hormone

became a major controversy in the battle over biotechnology generally. This section will focus only on the small role that NEPA played or could have played in shaping the FDA's regulation of rbST.

In the 1930's, research demonstrated that cows injected with bovine somatotropin (bST), a naturally occurring hormone in cows, produced more milk than untreated cows.¹⁴⁷ In the 1980's, with the advent of new genetic technologies, researchers were able to isolate the gene that produces bST and produce it commercially for large scale usage.¹⁴⁸ The technology used involves splicing the cow's bST into the DNA of an E. coli bacteria.¹⁴⁹ That bacteria can then be grown in fermentation tanks, producing vast quantities of the new synthetic hormone (rbST).¹⁵⁰ When this hormone is injected into cows, milk production is increased by an average of 12 percent.¹⁵¹

As an animal drug, rbST falls squarely within the jurisdiction of the FDA. Before rbST can be used commercially, the FDA must approve an new animal drug application to ensure the safety of the product both for animals and for humans.¹⁵² The hormone presented several potential risks. For the cows, rbST increases the risks of reduced pregnancy rates, ovarian cysts, uterine disorders, and decreased gestation periods and lower birth weight for calves.¹⁵³

The hormone also may cause increased bovine body temperatures, indigestion,

¹⁴⁷See Elie Gendloff, Stauber v. Shalala: Are Environmental Challenges to Biotechnology Too Difficult?, 4 Wis. Env'tl. L. J. 41, 44 (1997).

¹⁴⁸Id.

¹⁴⁹See David Aboulafia, Pushing rbST: How the Law and the Political Process Were Used to Sell Recombinant Bovine Somatotropin, 15 Pace Env'tl. Rev. 603, 605 (1998).

¹⁵⁰Id.

¹⁵¹See Karen G. Herman, Issues in the Regulation of Bioengineered Food, 7 High Tech. L. J. 107, 112 (1992).

¹⁵²See Section III(B) *supra*.

¹⁵³See Stauber v. Shalala, 895 F. Supp 1178, 1183 (W.D. Wis 1995)

bloating, diarrhea, enlarged hocks, hoof rot, enlarged lesions and injection site swelling.¹⁵⁴ Additionally, rbST increases the risk of mastitis, a bacterial infection of the udder which requires treatment by antibiotics to keep milk edible by humans.¹⁵⁵

There are two direct health risks posed by rbST in humans. The growth hormone gets passed into the cow milk and therefore is directly ingested by humans. However, there is evidence that rbST breaks down quickly in human stomachs and the hormone is not active in humans.¹⁵⁶ The other direct risk posed by rbST is that it stimulates the production of another hormone, insulin-like growth factor (IGF-1) which gets passed on in increased levels to milk.¹⁵⁷ This hormone is active in humans and it is not destroyed by pasteurization.¹⁵⁸ Short-term laboratory studies on rats have indicated that there are may be negative effects on the digestion system by IGF-1. Finally, there is an indirect risk posed by rbST. Because rbST increases the risk for mastitis, there is a greater risk that the antibiotics used to treat the disease will end up in milk.¹⁵⁹ But state and local governments already regulate milk for antibiotic presence and so this issue went largely unaddressed by the FDA.¹⁶⁰

The FDA evaluated all of these forms of risk and determined that any risk

¹⁵⁴Id.

¹⁵⁵Id.

¹⁵⁶See Gendloff, supra note 147, at 45.

¹⁵⁷Id.

¹⁵⁸Id.

¹⁵⁹Id.

¹⁶⁰Id. For a more detailed discussion of the potential health risks of rbST, see Aboulafia, supra note 149, at 626-40.

was manageable and not severe enough to deny approval. In its study and evaluation of the health risks to cows, the FDA concluded that the risk to cattle was manageable and the NIH reported that the effects of rbST on dairy cows appeared to be minimal.¹⁶¹ Similarly, the FDA concluded that there was only a very slight increase in the occurrence of mastitis in cows.¹⁶² However, there is substantial disagreement over how severe this risk actually is.¹⁶³ The FDA determined that rbST was safe for human consumption and did not even require Monsanto, the primary manufacturer of rbST to develop a testing regime to detect the actual amount of residue in milk.¹⁶⁴ In examining the potential effects of IGF-1, the FDA concluded that there was no evidence that IGF-1 harms humans at all and the substance is simply digested.¹⁶⁵ Further, the actual level of the hormone is similar to that found in human milk.¹⁶⁶ Finally, as noted above, the FDA relied on existing state and local regulatory systems for testing for antibiotics in milk to ensure that the milk supply is free from antibiotic residues.¹⁶⁷ Given the results of its testing, the FDA concluded that the milk from rbST cows was essentially the same as that from untreated cows and approved the use of rbST in dairy cows in late 1993.¹⁶⁸

¹⁶¹See Aboulafia, supra note 149, at 622.

¹⁶²Id.

¹⁶³Other sources including the General Accounting Office and private studies found the incidence of mastitis to be substantially higher and perhaps somewhere between a seventy-nine and nineteen percent increase. See Aboulafia, supra note 149, at 627.

¹⁶⁴Id. at 614.

¹⁶⁵Id. at 633. Again, this conclusion has been contested by various studies not conducted by the FDA. Other studies found evidence of risk of cancer, fetal development, renal effects, and interacting with other human diseases. See id. at 634.

¹⁶⁶Id.

¹⁶⁷Id. at 631.

¹⁶⁸Id. at 615. There is much more ‘behind the scenes’ in the approval of rbST including controversies over labelling, improper influences within the agency, and Congressional studies. For a detailed, yet critical, history of the FDA’s experience in studying, approving, and regulating rbST, see generally, id.

It is within the context of the widespread use of a drug that the FDA concluded was safe for use but that some feared was harmful or insufficiently studied that consumers brought a suit against the FDA, challenging its approval of rbST. In Stauber v. Shalala, consumers challenged the FDA's approval of rbST on three grounds: 1) the FDA did not consider the health and safety issues related to the use of rbST, 2) the FDA failed to require mandatory labeling of products with milk from cows treated with rbST, and 3) the FDA failed to conduct an adequate EA or EIS to determine the environmental impact of rbST.¹⁶⁹ The first two claims are based on alleged violations of the FDCA itself by the FDA for not adequately applying its own safety criteria to the approval process. The third claim is, obviously, a NEPA challenge to the approval. On the first claim, the district court found that the FDA properly considered the health and safety effects on both cows and humans.¹⁷⁰ The court held that while the consumer-plaintiffs were able to point to studies that disagree with the FDA results, FDA review did not fail the deferential arbitrary and capricious review standard.¹⁷¹ In its opinion, the court emphasized that the FDA is not required to find rbST safe at a "zero-risk" threshold, although it stated some doubts about the "manageable risk approach."¹⁷² The court also found that the plaintiffs labeling claim was without merit.¹⁷³ The FDA's approach did not required labeling for products with rbST milk and further required that products with non-rbST milk

¹⁶⁹Stauber v. Shalala, 895 F. Supp. 1178, 1182 (W.D. Wis. 1995).

¹⁷⁰Id. at 1191.

¹⁷¹Id.

¹⁷²Id. at 1191-92.

¹⁷³Id. at 1193.

not be labeled ‘growth hormone free’ without a disclaimer.¹⁷⁴ The court held that these decisions were rational under the statute¹⁷⁵ and survive arbitrary and capricious review.¹⁷⁶

The plaintiffs’ NEPA claim involved three alleged violations including a novel requirement that the FDA consider the socioeconomic effects of the product in its environmental review. When Monsanto applied for an NDA it submitted an EA, as required by FDA regulations. In response to that EA, the FDA issued a FONSI.¹⁷⁷ The environmental assessment, the content and scope for which the agency assumed responsibility, concluded that rbST would not affect land use patterns or structural trends in the dairy market.¹⁷⁸ The EA and FONSI also found that there were no environmental impacts concerning the biotechnological aspects of the drug’s production.¹⁷⁹ However, neither the EA nor the FONSI addressed the human health concerns raised by the potential for IGF-1 residue or antibiotic residue.¹⁸⁰ The EA and FONSI also failed to address a number of alternatives to approval, such as delaying approval for more study or approving a lower dose. The plaintiffs’ NEPA claim focuses on these two omissions as well as a third one. The plaintiffs’ alleged that NEPA requires the FDA’s EA to address the socioeconomic effects of rbST on dairy farmers.¹⁸¹

¹⁷⁴For example, a recently produced yogurt container had the following language, “We oppose rGBH (synthetic Bovine Growth Hormone [rbST]). The family farmers who supply our milk and cream pledge not to treat their cows with rBGH. According to the FDA, no significant difference has been shown, and no test can no distinguish between milk from rGBH treated cows and untreated cows.”

¹⁷⁵21 U.S.C. §343(a)(1) (prohibited misleading labeling) and 21 U.S.C. §321(n) defining labeling requirements for advertising purposes.

¹⁷⁶Stauber, 895 F. Supp at 1193.

¹⁷⁷Id. at 1186.

¹⁷⁸Id.

¹⁷⁹Id.

¹⁸⁰Id.

¹⁸¹Id. at 1194.

The extent to which NEPA requires agencies to examine the socioeconomic impacts is closely tied to the question of whether NEPA requires an examination of health effects. Several cases before Stauber have traced the contours of a ‘socioeconomic effects’ doctrine.¹⁸² The ‘rule’ is that socioeconomic effects need only be considered by an EIS when there is enough primary evidence of other environmental impacts to trigger an EIS.¹⁸³ In his article Dougherty argues that this ‘rule’ is somewhat inconsistent with NEPA’s requirement to examine human health effects.¹⁸⁴ Dougherty points to NEPA’s legislative history which discusses the importance of the right to a healthful human environment to support this claim.¹⁸⁵ Thus the FDA’s obligation to consider the socioeconomic effects of rbST could be linked to the FDA’s obligation to consider human health effects under NEPA.

The decision in Stauber demonstrates the limitations of NEPA in regulating products whose main ‘environmental’ concerns overlap directly with the concerns of the FDA’s statutory mandate. The court found that the FDA was not required to issue an EIS on the health effects of rbST because the FDA already had evaluated health and safety effects in its review of the NDA.¹⁸⁶ In so holding, the court relied on regulations promulgated by the CEQ which allows agencies to combine another agency document with NEPA, to fully satisfy

NEPA.¹⁸⁷ When the ‘environmental’ concerns to be addressed by an EA or EIS

¹⁸²See James B. Dougherty, The Application of NEPA to Agency Actions Affecting Human Health, 13 *Envtl. L. Rep.* 10179, fn. 30 (1983) (listing cases).

¹⁸³See id. at *7.

¹⁸⁴Id.

¹⁸⁵Id. at *3-*4

¹⁸⁶Stauber, 895 F. Supp. at 1195.

¹⁸⁷Id.; see 40 C.F.R. §1506.4 (1999).

are the human health effects of a project, the FDA's own processes are sufficient to evaluate these issues without reliance on NEPA. The court held that requiring the EA itself to contain the health and safety information from the FDA's studies in response to the NDA would amount to simple paperwork duplication and not advance NEPA's substantive goals.¹⁸⁸ The court flatly rejects, therefore, the claim that an EIS is required to consider the socioeconomic effects of rbST because there is no link to any other independent grounds for an EIS.¹⁸⁹ Put simply, socioeconomic effects on their own are not enough to trigger NEPA. This holding is based both on regulations promulgated by the CEQ describing this interrelatedness requirement and by the FDA excepting pure socioeconomic effects from EAs.¹⁹⁰

The decision in Stauber spurred a great deal of analysis of the entire process of the approval of rbST, as well as the general regulatory framework surrounding the control of biotechnology products. Because of the overlap between NEPA's human health mandate and that of the FDA, Stauber indicates that NEPA might not be the most successful mechanism to ensure that certain environmental concerns, including human health, are independently examined by FDA decision making. The next section will examine efforts to clarify an increasingly complex regulatory environment before the following section returns to the issue of the FDA, NEPA and biotechnology.

¹⁸⁸Stauber, 895 F. Supp. at 1196.

¹⁸⁹Id. at 1194.

¹⁹⁰Id.; see 40 C.F.R. §1508.14 (1999); 50 Fed. Reg. 16636 (1985).

E. Round 5: Regulatory Reform and the FDCA Modernization Act of 1997

In 1997, Congress enacted significant revisions to the entire FDCA, collectively entitled the Modernization Act of 1997.¹⁹¹ The revisions touched upon every aspect of the FDA’s regulation of food, drugs, and all the other areas of its jurisdiction. Section 411 of the act states, “notwithstanding any other provision of law, an environmental impact statement prepared in accordance with the FDA regulations in 21 C.F.R. Part 25 shall be considered to meet the requirements for a detailed statement under section 102(2)(c) of the National Environmental Policy Act of 1969.”¹⁹² The meaning behind this somewhat cryptic provision is not apparent unless viewed in a larger context of regulatory reform. In 1995, as part of implementing Vice President Gore’s National Performance Review, President Clinton issued initiatives that were designed to streamline the FDA’s regulatory policies. In 1997 (before the Modernization Act), in response to those initiatives, the FDA amended its regulations governing compliance with NEPA. This section will examine each of these steps to analyze how regulatory reform has altered the relationship between the FDA and NEPA.

In 1993, Vice President Al Gore undertook a major review of the administration of the federal government in an effort to reduce needless expenditures and improve functioning of bureaucracies. The project involved each cabinet department and 10 agencies, examining every aspect of how the government conducts

¹⁹¹Pub. L. No. 105-115, 111 Stat. 2296-2380 (1997) (“Modernization Act”).

¹⁹²Modernization Act §411; 111 Stat. 2373 (1997); 21 U.S.C. §746 (1999).

itself, from procurement to spending, reporting, employee management, customer service and productivity. The result of this investigation was a report present by the Vice President, entitled the National Performance Review.¹⁹³ The entire National Performance Review involved several volumes, including explanations of recommendations for each department or agency. The direct recommendations for the FDA involved integrating the two agencies responsible for food safety and allowing the FDA to collect fees for its inspection and approval processes for food, drugs, and devices.¹⁹⁴ As a separate part of Vice President Gore's reinventing government initiative, the FDA undertook a comprehensive review of its own procedures and administration.¹⁹⁵

One of the recommendations that emerged from that process was an initiative to reduce the burden of EAs on the approval process of food and drugs. The initiative stated that its goals were to accelerate the approval process of food and drug review and to bring products to the market sooner without sacrificing safety or quality.¹⁹⁶ In overviewing the major regulatory reform initiatives, the report recommended, "[e]xcluding drug and biologic manufacturers from requirements for most environmental assessments, which currently cost tens of thousands of dollars each time a new product is developed yet provide no real benefit to the environment."¹⁹⁷ The report states that while EAs cost between

¹⁹³Al Gore, Creating a Government that Works Better and Costs Less, National Performance Review, Washington, D.C. (1993) (National Performance Review).

¹⁹⁴Id. at 141.

¹⁹⁵Bill Clinton & Al Gore, Reinventing Drug and Medical Device Regulations, National Performance Review, Washington, D.C. (1995). The FDA references a similar companion, Reinventing Food Regulations (1996), however, this volume was not listed or available anywhere in the Harvard University Library System. See 62 Fed. Reg. 40570 (1997).

¹⁹⁶Id. at 2-4.

¹⁹⁷Id. at 5.

forty and one hundred and fifty thousand dollars each, virtually all of them result in the FDA issuing a FONSI.¹⁹⁸ Thus the report recommends increasing the number of categorical exclusions from the EA and EIS requirements mandated by NEPA and CEQ. To justify this initiative, the report declares, “[t]he FDA believes that nearly all product approvals will qualify for categorical exclusion. For example, virtually all drug approvals would result in only minute releases of the drug into the environment as a result of human use and such releases would not be environmentally significant.”¹⁹⁹ The report recognizes the FDA’s experience with taxol, but concludes that in such circumstances an EA or EIS should be prepared through an “extraordinary circumstance” exception to FDA regulations.²⁰⁰ Tellingly, the stated impacts of these recommendations are “substantially benefit[ing] industry and . . . improv[ing] regulatory efficiency without having any adverse impact on public health or the environment. Industry would save [the costs] on each EA.”²⁰¹ Thus as a result of a project designed to “treat taxpayer dollars with respect,”²⁰² the FDA committed to initiatives designed to reduce the burden of complying with federal law in order to save private industry money.

In response to these initiatives, the FDA undertook a major revision of its regulations that govern NEPA compliance. After notice and comment rulemaking, those regulations were finalized in July of 1997.²⁰³ The most significant change

¹⁹⁸Id. at 14.

¹⁹⁹Id.

²⁰⁰Id.

²⁰¹Id. at 15

²⁰²National Performance Review, supra note 193, at 2.

²⁰³NEPA, Revision of Policies and Procedures, 62 Fed. Reg. 40570 (1997).

in the rules is perhaps the tone underlying those rules. Echoing the need to reduce regulatory hurdles, the introduction to the rule states, the regulation “increases the efficiency of the agency’s implementation of NEPA by substantially reducing the number of EAs required to be submitted by industry and reviewed by FDA and by providing for categorical exclusions for additional classes of actions that do not individually or cumulatively have a significant impact on the human environment. This final rule also makes the regulations more concise and useful to the public and regulated industry.”²⁰⁴ This tone shift is born out by subtle rewording of the introductory regulation. The former purpose section began by invoking NEPA as “the national charter for protection, restoration, and enhancement of the environment.”²⁰⁵ The new purpose section merely begins, “[NEPA] directs that to the fullest extent possible, the policies, regulations, and public laws of the United States shall be interpreted and administered in accordance with the policies set forth in NEPA. All agencies . . . shall comply with the procedures in [NEPA] except where compliance would be inconsistent with other statutory requirements.”²⁰⁶ It remains to be seen whether placing paramount emphasis on efficiency and simplicity will still serve the environmental goals NEPA was meant to protect.

With respect to the categories of actions that would normally require an EA, a side by side comparison of the old regulations to the new ones do not reveal large discrepancies. The only three categories eliminated by the new regulations are

²⁰⁴Id.

²⁰⁵21 C.F.R. §25.1 (1985); see Section IV(B) supra.

²⁰⁶21 C.F.R. §25.1 (1997). Note how this tone echoes the FDA’s interpretation of NEPA overturned in EDF v. Mathews.

the regulations relating to the control of communicable diseases, the approval of antibiotic application, and the approval and issuance of licenses for biological products.²⁰⁷ Of these categories that no longer require an EA, the broadest in scope appears to be the approval and licensing of biological products.²⁰⁸ The FDA regulates biological products under the Public Health Services Act.²⁰⁹ The Act defines biological products as including viruses, therapeutic serum, toxin, antitoxin, vaccine, blood, or blood component.²¹⁰ The Act primarily regulates the movement and labeling of these materials.²¹¹ Too little time has elapsed to see how these omissions could affect FDA decision making. Nor is it clear what environmental impact would result from any of these three categories of actions now that the industry or the agency may engage in these actions without first producing an EA.

The other significant category missing from the new regulations is a “catch all” provision that requires an EA for any other action not listed that might impact the environment.²¹² However, the FDA’s response to comments on that omission was that new section 25.21 obviates the need for a “catch all.”²¹³ It is yet unclear how often and under what circumstances the “extraordinary circumstances” clause will be invoked. In fact, one comment to the regulation

²⁰⁷Compare 21 C.F.R. §25.20 (1997) with 21 C.F.R. §25.22(a)(13), (15), (16) (1985).

²⁰⁸21 C.F.R. §25.22(16) (1985).

²⁰⁹See 42 U.S.C. §262 (1999) (regulation of biological products).

²¹⁰Id. §262(a).

²¹¹Id.

²¹²21 C.F.R. §25.22(a)(19) (1985).

²¹³See 62 Fed. Reg. at 40572. 21 C.F.R. §25.21 (1997) reads, “as required under 40 C.F.R. §1508.4, the FDA will require at least an EA for any specific action that ordinarily would be excluded if extraordinary circumstances indicate that the specific proposed action may significantly affect the quality of the human environment.”

feared that it would be called upon too frequently so that NEPA would “creep” into expanding areas.²¹⁴ The FDA iterated its position that the “extraordinary circumstances” clause is reserved for truly exceptional circumstances.²¹⁵

The most significant change in the 1997 revisions was the expansion of the categorical exclusions. Two new categorical exclusions exempt EAs on all forms of NDAs if the action does not increase the use of the active ingredient or the increase will be minute (<1 part per billion).²¹⁶ The categorical exclusions now cover any NDA for substances that occur naturally in the environment if “the action does not alter significantly the concentration or distribution of the substance . . . in the environment.”²¹⁷ The new regulations also exempts any action on an IND.²¹⁸ The regulations contain several new exemptions designed to free most food additive petitions from NEPA process,²¹⁹ particularly additives that are part of packaging.²²⁰ The issuance, repeal, or amendment of a food standard are also subject to categorical exclusion.²²¹ Furthermore, the new regulations relating to animal drugs largely mirror those for human drugs so that NADA applications which either will not enter the human food chain or do not alter the concentration or distribution of a substance are free from EAs.²²²

The FDA’s desire to expand the coverage of categorical exclusions may have

²¹⁴62 Fed. Reg. at 40573.

²¹⁵Id.

²¹⁶21 C.F.R. §25.31(a)(b) (1997).

²¹⁷Id. §25.31(c).

²¹⁸Id. §25.31(e).

²¹⁹Recall that even proposed actions that purportedly fall within one of the categorical exclusions must include a statement explaining why that action fits the definition of the categorical exclusion. See 21 C.F.R. §25.15 (1997).

²²⁰Id. §25.32(i), (j), (m), (o).

²²¹Id. §25.32(a). A food standard is the definition of identity, quality, and container fill for food so that a can of peas actually contains peas that meet a certain quality and that is filled to a reasonable level within the can. See 21 U.S.C. §341 (1999).

²²²21 C.F.R. §25.33(a)(6-7), (c), (d), (e).

overzealously excepted from regulation the very categories that have proved problematic in the past.²²³ For instance, the blanket categorical exclusion for all INDs seems problematically broad, especially given the experience with taxol.²²⁴ The FDA explains, “the agency’s experience has demonstrated that significant environmental effects would not occur because the investigational use is limited and controlled. The dosing regimen for investigational drugs.. results in an environmental introduction [that is below the 1ppb triggering threshold].”²²⁵ In fact, the FDA addressed concerns about the taxol issue raised in the comments by reiterating that the Pacific Yew is specifically protected by a rule requiring EAs for most actions involving the tree.²²⁶ However, to protect the specific case of the Pacific Yew alone is shortsighted – the FDA’s answer does not address how the regulations will deal with the next drug that is derived from a limited natural resource. Indeed, a complete normative debate over these regulations would consist largely analyzing speculative scenarios in which an action that is now categorically excluded could impact the environment. Without much empirical information to analyze, however, whether the FDA struck the right balance between efficiency and protection remains an unresolved issue.

While the theoretical debate as to whether the FDA acted properly in its regulatory revisions may continue, Congress answered the question definitively. In

light of the new regulations, the effect of §411 of the Modernization Act is

²²³To grasp fully the import of these categorical exclusions would require an in-depth appreciation of the FDA regulatory scheme that is beyond the scope of this paper. The response to comments clarifying these regulations occupy 22 pages in the Federal Register, 62 Fed. Reg. 4570-4592.

²²⁴See Section IV(C) *supra*.

²²⁵62 Fed. Reg. at 40578.

²²⁶*Id.* at 40573. The regulation at issue was published in 61 Fed. Reg. 58694 (1996) which was discussed in Section IV(C)

clear. By stating that an EIS prepared in accord with 21 C.F.R. Part 25 shall satisfy the procedural requirements of §102(2)(c) of NEPA, Congress was essentially validating the regulatory reforms promulgated by the FDA. Those who believed that the new regulations were too heavily focused on efficiency than in complying with NEPA were foreclosed from challenging the regulations in court.²²⁷ Though the legislative history the Modernization Act contains virtually no discussion of this section, there is enough evidence that the effect just mentioned was precisely what Congress intended. The introductory language of the new section, “notwithstanding any other provision of law” was included to indicate that §411 is valid despite what NEPA may require – even if some of 21 C.F.R. Part 25 conflicts with NEPA.²²⁸ This evidence is bolstered by an explicit statement to the same effect by the conference report.²²⁹ The report also approved of the FDA’s goals of eliminating unnecessary paperwork and delays in enacting the new regulations.²³⁰ Despite this ringing endorsement of the new regulations, the statute does not preclude judicial enforcement of the EAs or EISs themselves and the FDA can modify the regulations as it sees fit, in consultation with the CEQ.²³¹ Other than these minor clues, the extensive documents constituting the legislative history of the Modernization Act contain precious little information on §411.²³² Indeed, it is not clear that outside of

²²⁷This is not meant to imply that there were challenges waiting in the wings that were cut off by the enactment of the Modernization but merely that the Act officially sanctioned the new regulations (i.e. an EDF v. Mathews -type suit is foreclosed by this law.)

²²⁸138 Cong. Rec. H8467 (daily ed. October 7, 1997).

²²⁹H.R. Rep. No. 105-399 (1997), reprinted in 1997 U.S.C.C.A.N. 2880, 2892.

²³⁰Id.

²³¹Id.

²³²See e.g., H.R. Rep. No. 105-310 (1997) (section by section analysis of the act, simply restates the section with no comment); 129 Cong. Rec. S9811-9850 (daily ed. September 24, 1997) (major floor debate of Modernization Act contains no mention of this section).

the drafting committee, the effect, importance or meaning of this section was understood by Congress.²³³

The era of regulatory reform has impacted the interaction between the FDA and NEPA. First the FDA cut back on the extent of its compliance with NEPA and then Congress accepted those cut backs.²³⁴ Initially, it appears that the FDA has not opened up huge loopholes by which environmentally significant action could sneak through the FDA decision making process unchecked. While the controversies discussed in this paper have highlighted how FDA action can impact the environment, these cases are the exception not the rule. For the most part, FDA action has little environmental impact and these regulations seek to recognize that fact.

²³³See S. Rep. No. 105-43 (1997) (stating that the new section establishes that no action taken by the FDA shall be subject to an environmental impact assessment, and EIS, or other environmental documentation unless the FDA demonstrates that there is reasonable probability that the environmental impact of the action is substantial and that consideration of the impact will directly affect the decision on that action). This statement conflicts with the regulations enacted by the FDA itself which clearly require EAs for several categories of action, regardless of the potentiality of significant impact, or the effect the impact will have on decision making. Again, other than this confusing statement, the entire Senate report contains no further discussion of the section.

²³⁴There is another potential motivation behind §411. The conference report, in discussing §411, states that the “EPA cannot dictate, promote, or encourage a policy preference for disposal by incineration of metered dose inhalers (MDIs), but it shall allow such contents to be reused, recycled, or recaptured until Congress says.” H.R. Rep. No. 399-105. Essentially what this statement is referring to are efforts by the EPA to eliminate metered dose inhalers that contain CFCs so as to comply with the Montreal Protocol on Substances That Deplete the Ozone Layer. The FDA has taken steps to comply with proposed efforts to phase out MDIs which contain CFCs. 62 Fed. Reg. 40577. Several members of Congress expressed concern that this measure might eliminate effective delivery of asthma medication, or increase costs unacceptably. See e.g., 123 Cong. Rec. E1766 (daily ed. September 16, 1997) (statement by Patrick Kennedy of Rhode Island); 138 Cong. Rec. H8480 (daily ed. October 7, 1997) (statement by Christopher Smith of New Jersey). Thus one of the goals of §411 appears to be to temporarily halt EPA action on the subject and allow MDIs with CFCs to be phased out as cheap and effective alternatives become available. See 140 Cong. Rec. H8809 (daily ed. October 9, 1997). Why this meaning is buried in legislative history and not all apparent from the statutory language itself is not at all clear.

F. Round 6: The Challenge of Biotechnology and Beyond

One of the greatest regulatory challenges now facing agencies is the increasing use of products designed by biotechnology. Biotechnology refers generally to the use of advancements in DNA sequencing and gene splicing to alter various biological entities, whether it be pathogen-resistant plants or cloned sheep. Each agency is scrambling in its own right to figure out first if special regulation is needed and if so, how to go about regulating these technologies. To discuss how the FDA does and should regulate biotechnology is a separate topic about which a great deal could be written. Similarly, to contemplate what role, if any, NEPA should play in regulating the environmental impacts of biotechnology would also warrant independent consideration. But the story of how the FDA and NEPA interact in regulating biotechnology is no story at all – the agency has not identified any unique role for NEPA separate from the role it already plays, as discussed above. This decision (or lack of decision) is in keeping with the role that the Environmental Protection Agency (EPA) has identified for NEPA in regulating areas of that agency’s jurisdiction – none. This section will briefly overview the regulation of biotechnology and highlight, through the example of Bt corn, how NEPA’s procedures could inform FDA decision making so as to avoid environmental harm.

Despite the relatively recent insurgence of technologies that can manipulate genes, the question of how various agencies should regulate the products of these technologies was addressed over 14 years ago. In 1986, the federal gov-

ernment, through the Office of Science and Technology Policy, published the Coordinated Framework for the Regulation of Biotechnology.²³⁵ The purpose of the Coordinated Framework was to figure how the overlapping areas of various agencies jurisdictions should interact to regulate biotechnology.²³⁶ Above all else, the Coordinated Framework sought to avoid creating another agency, a super-regulator, to oversee the regulation of biotechnology.²³⁷ By defining the scope of each agency's responsibility, the Coordinated Framework worked within existing statutory structures to coordinate regulation.²³⁸ The major agencies covered by the Coordinated Framework's guidelines are the National Institute of Health (NIH), the FDA, the EPA, and the Department of Agriculture. Also the Occupational Safety and Health Administration, the Department of Defense, the National Science Foundation, and the Department of Energy play lesser roles in the guidelines.²³⁹ The Coordinated Framework states that NEPA continues to impose the procedural requirements of an EA or EIS for any agency action affecting the environment.²⁴⁰ Criticism and analysis of the Coordinated

²³⁵Coordinated Framework for Regulation of Biotechnology, 51 Fed. Reg. 23302 (1986) ("Coordinated Framework").

²³⁶The Coordinated Framework states, "[t]he underlying policy question was whether the regulatory framework that pertained to products developed by traditional genetic manipulation techniques was adequate for the products obtained with the new techniques. A similar question arose regarding the sufficiency of the review process for research conducted for agricultural and environmental applications." 51 Fed. Reg. 23302 at *3.

²³⁷In 1992, the Coordinated Framework was updated by the so-called "Scope" document published by OSTP. The Scope document was designed to fill in the gaps of the Coordinated Framework. In response to a fear that agencies would overzealously regulate anything that is in some way biotechnological, the document constrains the exercise of agency discretion in regulation of biotechnology. See Aboulafia, *supra* note 149, at 609. Importantly, the Scope document allows agencies to skirt the regulatory process altogether by declaring that a genetically engineered product is sufficiently similar to its natural counterpart that it is not new and not subject to new regulation. 57 Fed. Reg. 6757, 6759 (1992).

²³⁸See Linda Maher, *The Environment and the Domestic Regulatory Framework for Biotechnology*, 8 J. Envtl. L. & Litig. 133, 137-38 (1993).

²³⁹*Id.* at 139.

²⁴⁰51 Fed. Reg. 23302 at *5.

Framework and the overall regulatory schemes for biotechnology have been covered heavily in legal literature.²⁴¹ However, this paper will briefly summarize the response of the FDA and the EPA to the Coordinated Framework to outline how each agency plans to regulate the products of biotechnology.

The FDA's basic approach to biotechnology is that no new procedural or regulatory innovations are required to deal with the products of biotechnology.

In a document published the same time as the Coordinated Framework, the FDA outlined a policy statement for regulating biotechnology. The approach is simple:

Although there are no statutory provisions or regulations that address biotechnology specifically, the laws and regulations under which the agency approves products place the burden of proof of safety as well as effectiveness of products on the manufacturer. . . . In this notice, FDA proposes no new procedures or requirements for regulated industry or individuals. Rather, the administrative review of products using biotechnology is based on the intended use of each product on a case-by-case basis.²⁴²

The rest of the FDA statement demonstrates how existing procedures to regulate drugs, animal drugs, medical devices and food adequately screen for potential health effects that may be introduced by biotechnology. For instance, the FDA acknowledges that a food substance which is generally recognized as

²⁴¹See e.g., William von Oehsen III, Regulating Genetic Engineering in an Era of Increased Judicial Deference: A Proper Balance, 40 Admin. L. Rev. 303 (1988); Lisa E. Comer, Genes Made in the USA, 7 Temp. Env'tl. L. & Tech. J. 63 (1988); James Maryanski, Prospects for the Safety Evaluations of Foods in the United States of America in Connection with Biotechnology, 256 PLI/Pat 243 (1988); Karen Goldman Herman, Issues in the Regulation of Bioengineered Food, 7 High Tech. L. J. 107 (1992); Aboulafia, supra note 149, 15 Pace Env'tl. L. Rev. 603 (1998). Generally, these articles offer an agency by agency review of biotechnology regulation, as well as highlighting some of the major substantive challenges that arise in the biotechnology context. The consensus among most is that the current scheme does not do enough to address the issues of biotechnology either because the technologies advance too quickly or the statutes being used are not designed to tackle the unique issues raised. These articles explain the role of the FDA and EPA in more detail than presented here.

²⁴²Statement of Policy for Regulating Biotechnology Products, 51 Fed. Reg. 23309 (1986) at *3 (emphasis added).

safe (GRAS)²⁴³ may lose that status if it was produced or modified by biotechnology.²⁴⁴ However, no unique approach is required to approve a food additive that is produced or modified by biotechnology, rather, the FDA will apply the same rules and procedures as it would to any GRAS petition.²⁴⁵ The agency does outline several detailed scientific criteria that the agency will consider when reviewing products that involve biotechnology such as rDNA manipulation.²⁴⁶ Fundamentally, though, the FDA's approach to regulation remains unchanged.²⁴⁷ NEPA and environmental considerations will presumably continue to be accounted for through the regulations discussed above. The FDA makes no mention of special environmental considerations derived from biotechnology.

The EPA promulgated a similar statement regarding how the agency intends to regulate biotechnology. The document is much more detailed and substantial than that of the FDA because the EPA (due to its subject matter) enacted substantial regulatory and policy initiatives to comply with the Coordinated Framework.²⁴⁸ For the purposes of this paper, what is essential to the EPA's approach is that it does not identify any particular role for NEPA in regulating biotechnology. The EPA bases its biotechnology policies in two statutes, the

²⁴³21 U.S.C. §348 (1999) defines a food additive (subject to regulation under §348) in part as a substance that is a component or comes into contact with and is not generally recognized, among scientific experts, as safe for use under intended conditions.

²⁴⁴51 Fed. Reg. 23309 at *9.

²⁴⁵*Id.*

²⁴⁶*Id.* at *10-11.

²⁴⁷For an argument on how the FDA's labeling procedures ought to be altered when dealing with the products of biotechnology, see Kirsten S. Beaudoin, *On Tonight's Menu, Toasted Cornbread with Firefly Genes? Adapting Food Labeling Law to Consumer Protection Needs in* 83 Marq. L. Rev. 237 (1999).

²⁴⁸Statement of Policy, Microbial Products Subject to the Federal Insecticide, Fungicide and Rodenticide Act and the Toxic Substances Act, 51 Fed. Reg. 23313 (1986).

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA)²⁴⁹ and the Toxic Substances Control Act (TSCA).²⁵⁰ The two statutory schemes, directly administered by the EPA, are product-based regulations that allow the EPA to ban or limit production and use of certain substances.²⁵¹ The EPA uses these two statutes to regulate “microorganisms that will be used to degrade toxic pollutants, leach minerals, enhance oil recoveries, produce industrial chemical, and act as pesticides.”²⁵² As these functions indicate, the EPA is concerned directly with the release of biotechnological products into the environment. However, the EPA has not included NEPA in its scheme for regulating biotechnology. Though the EPA does not directly administer NEPA (since its duties are imposed on all Federal agencies) in the way it does FIFRA or TSCA, the agency could have endorsed NEPA as a powerful mechanism for controlling the environmental impact of biotechnological products. Such a statement would have sent a clear message to other agencies that NEPA’s framework should figure prominently in their regulatory schemes as well.

The current controversy and potential impact of the transgenic corn seed, Bt Corn, demonstrates how NEPA might have the potential to aid the FDA in its regulation of biotechnology. Bt Corn is a genetically engineered strain of corn that contains a gene from a bacterium, *Bacillus thuringiensis*, which renders the corn resistant to certain insect-pests, including the European corn borer.²⁵³

²⁴⁹7 U.S.C. §§136-136y (1999).

²⁵⁰15 U.S.C. §§2601-2671 (1999).

²⁵¹See Maher, *supra* note 238, at 158.

²⁵²51 Fed. Reg. 23313 at *4.

²⁵³See Sara M. Dunn, *From Flav’r Sav’r to Environmental Saver? Biotechnology and the Future of Agriculture*, International Journal of Environmental Law & Policy 145, 151 (1998).

Last year, approximately thirty percent of corn grown in the United States was Bt Corn.²⁵⁴ The strain of corn could save one to two billion dollars a year in lost farm revenue and increased production consistency by two hundred percent.²⁵⁵ However, after Bt Corn was approved by the Department of Agriculture and the EPA,²⁵⁶ a Cornell laboratory study revealed that pollen from Bt Corn killed the larvae of Monarch butterflies.²⁵⁷ The pollen from the corn spreads to milkweed plants, a favorite of the Monarch, which often grows next to corn fields.²⁵⁸ The other potential danger from this product is that insects can become resistant to the toxin in the corn.²⁵⁹ In response to these dangers, in January 2000, the EPA announced new restrictions on the use of Bt Corn. The EPA will require farmers to plant at least twenty percent conventional corn, preferably on the perimeters of fields to create buffer zones, in most regions.²⁶⁰

These profound environmental impacts, which could harm one of the most important species to the vitality of the ecosystems of North America or unleash generations of pesticide resistant insects, were completely overlooked in the approval process of Bt Corn.²⁶¹ Whether or not a proper EIS would have revealed the results of the Cornell study begs the question – the regulatory

²⁵⁴See EPA Places Restriction on Biotech Corn Plantings (last visited February 19, 2000) <<http://www.cnn.com/2000/FOOD/news/01/07/biotech.corn.ap/index.html>>.

²⁵⁵See Dunn, *supra* note 253, at 151-52.

²⁵⁶Receipt of an Application for an Experimental Use Permit Amendment for a Transgenic Plant Pesticide, 59 Fed. Reg. 65358 (1994).

²⁵⁷J. E. Losey, et. al., *Transgenic Pollen Harms Monarch Larvae*, 399 Nature 214 (1999).

²⁵⁸*Id.*

²⁵⁹Plant Pesticides Resistance Management, 62 Fed. Reg. 19115, 19115 (1997).

²⁶⁰See note 254, *supra*.

²⁶¹There is some dispute as to what the real world impact of the Bt pollen would be on actual Monarch butterfly populations since the Cornell study was a laboratory setting. See *The World Is Still Safe for Butterflies*, Wall St. J., June 25, 1999 at A18.

process contemplated by the Scope Document and the Coordinated Framework completely failed to identify a potential ecological catastrophe because the issue was never even considered. This failure could be analyzed from the perspective of the EPA, the Department of Agriculture, or any other agency responsible for regulating biotechnology, but what is relevant here is that of the FDA.

Though the FDA seems only remotely involved in Bt Corn, the agency's interaction with NEPA could have played a larger role. According to its biotechnology statement, the FDA is responsible for ensuring the safety for human consumption of Bt corn.²⁶² Had the FDA applied its regulations enacting NEPA more strictly, perhaps this approval process would have triggered an EA and perhaps an EIS. However, since FDA regulations generally categorically exclude GRAS petitions, no such impact review would have been required.²⁶³ Of course, the EPA and the Department of Agriculture should share the bulk of the responsibility – as in the taxol controversy, it is likely that FDA should have incorporated by reference an EA prepared by one of the main regulatory agencies implicated by the product. But no such EA was prepared and the FDA did not require one on its own.

It is clear both from the Coordinated Framework and the policy statements of the EPA and the FDA that the direct statutory and regulatory duties imposed by the agencies' organic statutes are the mainstay of biotechnological regulation. However, the experience of Bt Corn merely serves as an example of the potential for the FDA and NEPA to interact successfully to regulate biotech-

²⁶²See note 242, *supra*.

²⁶³21 C.F.R. 25.32(k) (1997).

nology. The two are well suited for this challenge because many biotechnology products are either part of a drug or food and because NEPA already presents a statutory framework with which to analyze environmental impacts. Hopefully, the adverted danger of Bt Corn will force the FDA, and other agencies, to reevaluate the role that NEPA plays in accounting for the environmental impact of biotechnology.

V. Conclusion

The interactions between the FDA and NEPA have had a varied history. At times the FDA has struggled to find a place for NEPA in the agency's regulatory scheme while other times the FDA has appeared eager to advance the substantive goals of NEPA. What emerges from the history of the agency's interactions with NEPA is unequivocal evidence that the regulation of food and drugs can and does impact the environment. Those impacts are largest when environmental analysis slips through the regulatory cracks. Unfortunately, most recently those cracks have been deliberately expanded by the regulatory reform of the Modernization Act of 1997 and perhaps by the FDA's scheme to enact the Coordinated Framework. The experience of the FDA with taxol, rbST, and Bt Corn indicate that in an increasingly complex regulatory and technological setting, even the most innocuous agency actions may have drastic environmental impacts. That is not to say that the FDA's goals of increasing efficiency are not admirable or even necessary – streamlining the federal bureaucracy is an

impressive challenge. However, these goals must be kept in balance with NEPA's goals. NEPA's substantive aims and its procedural mandates are a powerful tool for ensuring that each agency conducts itself with some awareness of the larger potential of its actions. The NEPA framework is inherently flexible to allow the statute to protect the environment across regulatory settings and different time periods. Perhaps the main thrust of the recommended approach for the FDA in its interactions with NEPA is simply to let the statute do its work. The FDA should embrace NEPA's function as a gatekeeper. In that manner, the FDA can ensure not only that our food and drug supplies are safe, but also that we will continue to live in a healthful environment in which we can enjoy them.